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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,736	04/13/2004	Hironori Satoh	163852021000	4617

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Barry E. Bretschneider
Morrison & Foerster LLP
Suite 300
1650 Tysons Boulevard
McLean, VA 22102

EXAMINER

TOTH, KAREN E

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/822,736

Applicant(s)

SATO ET AL.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/13/04 & 11/01/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the limitation "a second adjustment unit" in line 6. There is insufficient antecedent basis for this limitation in the claim. For examination purposes, this claim will be treated as reading --an adjustment unit--.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 10-12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Oka'305 (US Patent Application Publication 2002/0161305).

Regarding claim 10, Oka'305 discloses a pulse wave measuring apparatus (element 8) comprising a pressure sensor that detects an intra-arterial waveform superficial of a patient's body (element 46) and a unit to determine whether the pressure

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holding the sensor against the body is appropriate, based on the sphygmographic waveform detected by the sensor (paragraphs [0031] and [0035]-[0037]).

Regarding claim 11, Oka'305 further discloses that the unit makes determination using a rising sharpness of a peak of the sphygmographic waveform (paragraph [0058]).

Regarding claim 12, Oka'305 further discloses a unit for adjusting the pressurization force (element 52), where the changes in the waveform after adjusting the pressurization force are included in the determination of an optimum pressurization force (paragraphs [0031] and [0035] -[0037]).

Regarding claim 15, Oka'305 discloses a program product causing a computer to execute control of a pulse wave measuring apparatus including a pressure sensor detecting an intra-arterial pressure waveform by acquiring a sphygmographic waveform detected with the pressure sensor (element 46) from the measuring apparatus and determining whether the pressurization force of the pressure sensor against a body surface is appropriate, based on the waveform (paragraphs [0031] and [0035] -[0037]).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1-4, 5-6, 9, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka'305 in view of Goto'726 (US Patent 6527726).

Regarding claims 1 and 4, Oka'305 discloses a pulse wave measuring apparatus comprising a pressure sensor that detects an intra-arterial waveform superficial of a patient's body (element 46) and a unit to determine whether the pressure holding the sensor against the body is appropriate, using the signal represented the detected pressure, which is subsequently filtered using a low pass filter, to make the determination (paragraphs [0026], [0031] and [0035]-[0037]). Oka'305 does not disclose using a direct current component of the pressure value to make the appropriateness determination.

Goto'726 teaches a blood pressure monitor comprising a low pass filter (element 20) that is used to extract a direct current component of a pressure signal for further analysis (column 11, lines 62-64), since it is well known in the art to use a low pass filter to extract direct current signal components.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Oka'305 and used the low pass filter to

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extract a direct current signal component, as taught by Goto'726, since it is well known in the art to use a low pass filter to extract direct current signal components for use in further analysis.

Regarding claim 5, Oka'305 further discloses that the device comprises a booster unit (elements 50 and 52) that alters the pressurization force by applying pressure at either a constant or arbitrary rate (paragraph [0036]).

Regarding claim 6, Oka'305 further discloses that the device comprises means for comparing the signal component at the time of pressure optimization with a signal component for after signal optimization, and for carrying out adjustment of the pressurization force so that the force does not exceed the optimal force (paragraph [0058]).

Regarding claim 9, Oka'305 further discloses that the device comprises a unit (element 82) for determining whether the pressurization force of the pressure sensor is appropriate based on a sphygmographic waveform (paragraph [0035]), and an adjustment unit (elements 50, 52, and 84) that adjusts the pressurization force after defining the optimum pressurization force based on the determination result (paragraphs [0036] and [0058]).

Regarding claim 14, Oka'305 discloses a program product causing a computer to execute control of a pulse wave measuring apparatus including a pressure sensor detecting an intra-arterial pressure waveform by acquiring a signal representative of the detected pressure (detected with the pressure sensor (element 46) from the measuring apparatus), filtering the signal using a low pass filter, and determining whether the

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pressurization force of the pressure sensor against a body surface is appropriate, based on the waveform (paragraphs [0026], [0031] and [0035] -[0037]). Oka'305 does not disclose using a direct current component of the filtered signal for pressure appropriateness determination.

Goto'726 teaches a blood pressure device comprising processor configured to use a low pass filter (element 20) to extract a direct current component of a pressure signal for further analysis (column 11, lines 62-64), since it is well known in the art to use a low pass filter to extract direct current signal components.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Oka'305 and used the low pass filter to extract a direct current component of the pressure signal, as taught by Goto'726, since it is well known in the art to use low pass filters to extract direct current signal components for use in further signal analysis.

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oka'305 in view of Goto'726, as applied to claims 1-4, 5-6, 9, and 14 above, and further in view of Callahan'244 (US Patent 5094244).

Oka'305 in view of Goto'726 discloses all the elements of the current invention except for acquiring the direct current component from an average value between predetermined intervals of pressure values output from the pressure sensor.

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Callahan'244 teaches a pulse wave sensor comprising acquiring a direct current component of a pressure signal as an average value between predetermined intervals (a single pulse wave) output from the pressure sensor (column 1, lines 27-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Oka'305 in view of Goto'726 and acquired the direct current component from an average value between predetermined intervals of pressure values output from the pressure sensor, as taught by Callahan'244, since it is merely the substitution of one equivalent signal processing method for another.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oka'305 in view of Goto'726, as applied to claims 1-4, 5-6, 9, and 14 above, and further in view of Amano'471 (US Patent Application Publication 2002/0065471).

Oka'305 in view of Goto'726 discloses all the elements of the current invention except for acquiring the direct current component from an intermediate point between a high and a low value in a predetermined interval of pressure values output from the pressure sensor.

Amano'471 discloses a pulse wave sensing apparatus that extracts a direct current component of a pressure signal as an intermediate point between predetermined high and low values (paragraph 390), since it's merely an alternate method of determining a direct current component from a pressure signal.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Oka'305 in view of Goto'726, and determined the direct current signal component as an intermediate point between predetermined high and low values, as taught by Amano'471, since it's merely an alternate method of determining a direct current component from a pressure signal.

9. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being obvious over Oka'305 in view of Goto'726, as applied to claims 1-4, 5-6, 9, and 14 above, and further in view of Sato'061 (US Patent Application Publication 2004/0193061).

Regarding claim 7, Oka'305 in view of Goto'726 discloses all the elements of the current claim except for the device comprising a suction unit for altering the pressurization force by reducing pressure at either an arbitrary or constant rate. Sato'061 teaches a pulse wave detecting apparatus comprising a negative pressure pump (suction section) (element 15) for reducing pressure at an arbitrary or constant rate, in order to better control the rate of depressurization.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Oka'305 in view of Goto'726 with a suction section for reducing pressure at an arbitrary or constant rate, as taught by Sato'061, in order to better control the rate of depressurization.

Regarding claim 8, Oka'305 further discloses that the device comprises means for comparing the signal component at the time of pressure optimization with a signal component for after signal optimization, and for carrying out adjustment of the

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pressurization force so that the force does not exceed the optimal force (paragraph [0058]).

10. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oka'305 in view of Goto'726, as applied to claims 1-4, 5-6, 9, and 14 above, and further in view of Zheng'540 (US Patent 5997540)

Regarding claim 7, Oka'305 in view of Goto'726 discloses all the elements of the current claim except for the device comprising a suction unit for altering the pressurization force by reducing pressure at either an arbitrary or constant rate.

Zheng'540 teaches a device with a pressurization cuff comprising a suction unit (elements 20 and 26) for reducing the pressurization force at an arbitrary or constant rate (column 7, line 64, to column 8, line 9), in order to better control the release of pressurization.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Oka'305 in view of Goto'726 with a suction unit for altering the pressurization force by reducing pressure at an arbitrary or constant rate, as taught by Zheng'540, in order to better control the release of pressurization.

Regarding claim 8, Oka'305 further discloses that the device comprises means for comparing the signal component at the time of pressure optimization with a signal component for after signal optimization, and for carrying out adjustment of the

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pressurization force so that the force does not exceed the optimal force (paragraph [0058]).

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 5497779 to Takaya, which discloses a similar device.

US Patent 5279303 to Kawamura, which discloses a similar device.

US Patent Application Publication 2004/0171941 to Narimatsu, which discloses a similar device.

US Patent 5873834 to Yanagi, which discloses a similar device.

US Patent 6022320 to Ogura, which discloses a similar device.

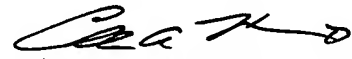
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Charles A. Marmor, II
SPE, Art Unit 3735